

REMARKS

Reconsider of the present patent application is respectfully requested. In this regard, the Office Action rejects independent claims 1, 10, 17, and 21 as being anticipated under 35 U.S.C. § 102 by U.S. Pat. No. 6,099,481 to Daniels. The remaining claims, with the exception of claims 8, 9, and 18, stand rejected either under § 102 to Daniels or under 35 U.S.C. § 103 based on a combination of U.S. Pat. No. 5,954,050 to Christopher and other cited references. Claims 8, 9, and 18 stand objected to as being dependent on a rejected base claim but would be allowable if rewritten in independent form.

Independent Claims 1, 10, 17, & 21

Under section 102, the general rule is that a claim is anticipated if “each and every element as set forth in the claim is found . . . in a single prior art reference.” Verdegaal Bros. v. Union Oil Co. of Ca., 2 U.S.P.Q.2d 1051 (Fed. Cir. 1987). Consequently, Daniels must set forth each and every element as found in independent claims 1, 10, 17, and 21. It is respectfully submitted that Daniels does not fulfill this condition.

Independent claim 1 is directed to a method of providing a breathing gas that includes the steps of:

increasing the breathing gas pressure provided to the patient breathing interface;

decreasing the breathing gas pressure provided to the patient breathing interface after a predetermined period of time; and

the increasing and decreasing of breathing gas pressure maintaining a positive pressure sufficient to sustain open the airway of a patient wearing the breathing interface. (Emphasis added).

Independent claims 10 and 17 are similar but of different scope. Independent claim 21 is also of different scope and includes the limitations of:

providing a **first positive airway pressure** to the patient breathing interface for a fixed period of time; and

upon the expiration of the fixed period of time providing a **second positive airway pressure** to the patient breathing interface. (Emphasis added).

It is respectfully submitted that Daniels fails to teach each and every limitation of independent claims 1, 10, 17, and 21.

Daniels is directed to “systems which **monitor** respiratory air flow, pressure and carbon dioxide levels, **process** those measurements to derive information about various respiratory-related functions and blood carbon dioxide levels, and **display** the measured and derived information.” (Col. 1, lines 9-14) (emphasis added). The Office Action asserts that Daniels teaches the claimed “increasing and decreasing of breathing gas pressure maintaining a positive pressure sufficient to sustain open the airway of a patient wearing the breathing interface” (claims 1, 10 & 17) and “providing a first positive airway pressure to the patient breathing interface for a fixed period of time; and upon the expiration of the fixed period of time providing a second positive airway pressure to the patient breathing interface” (claim 21). (See Office Action, page 3). In support of this assertion, the Office Action sites Daniels Figure 11 and the text associated therewith at column 10, line 19 through column 12, line 12. Daniels Figure 11 is reproduced below:

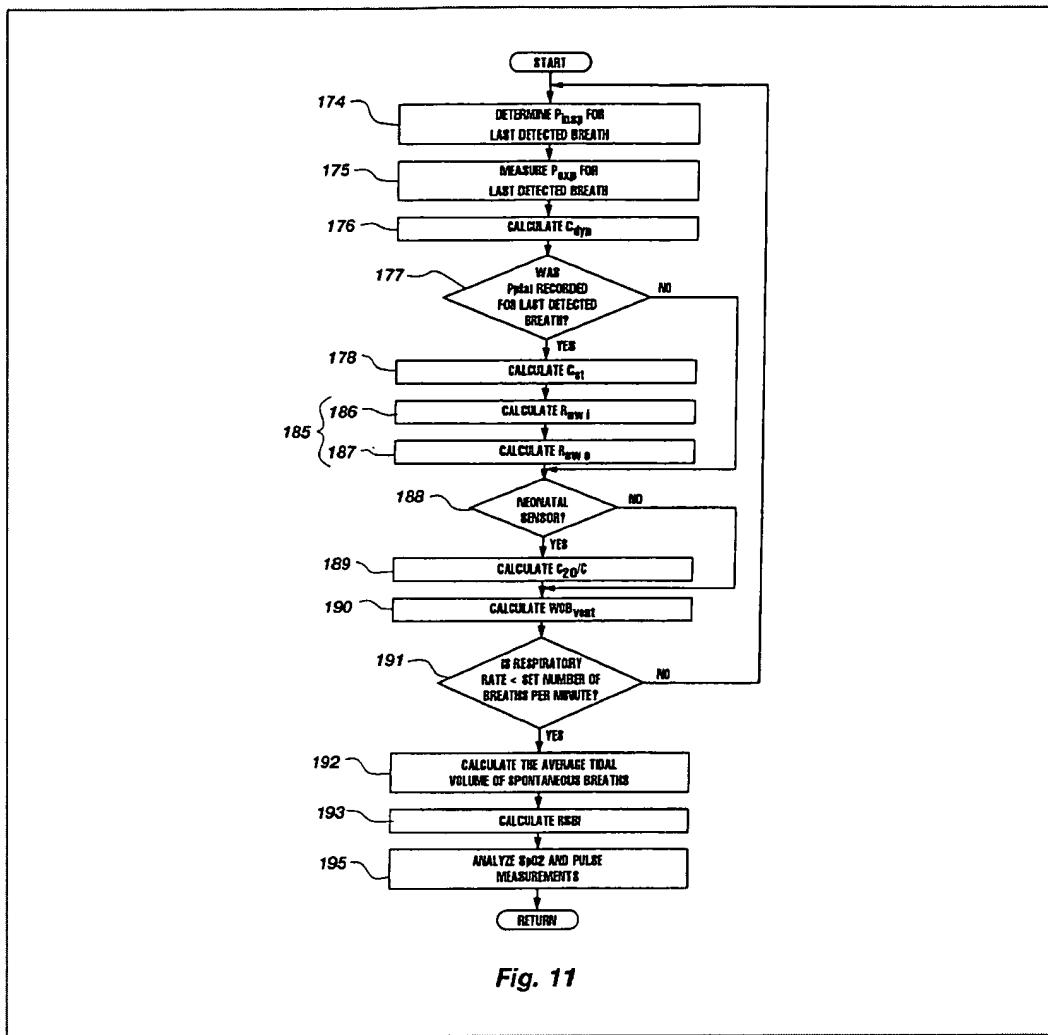


Fig. 11

Daniels describes Figure 11 as "a flow chart of a method of calculating various respiratory mechanic parameters." (Col. 2, lines 43-44). A review of Figure 11 and its associated text shows the calculation of various respiratory mechanic parameters such as, for example, dynamic compliance C_{dyn} , initial respiratory pressure P_{insp} , initial expiratory pressure P_{exp} , static compliance C_{st} , airway resistance during inspiration $R_{aw\ i}$, airway resistance during expiration $R_{aw\ e}$, compliance over the last 20% of patient breath's $C_{20/C}$, work of breathing done by a ventilator WOB_{vent} , rapid shallow breathing index $RSBI$, and the oxygen content of a patient's arterial blood SpO_2 . It is respectfully submitted that none of these parameters on their face nor Figure 11 as a whole teach or suggest the claimed "increasing and decreasing of breathing gas pressure **maintaining a positive**

pressure sufficient to sustain open the airway of a patient wearing the breathing interface” (claims 1, 10 & 17) or “providing a **first positive airway pressure** to the patient breathing interface for a fixed period of time; and upon the expiration of the fixed period of time providing a **second positive airway pressure** to the patient breathing interface” (claim 21). (Emphasis added).

Daniels states in the “Summary of the Invention” that “If a patient's respiration is controlled by a ventilator, the system of the present invention may also calculate respiratory mechanics characteristics.” (Col. 2, lines 8-11). It is respectfully submitted that this disclosure on its face also fails to teach or suggest the claimed “increasing and decreasing of breathing gas pressure **maintaining a positive pressure sufficient to sustain open the airway of a patient wearing the breathing interface**” (claims 1, 10 & 17) or “providing a **first positive airway pressure** to the patient breathing interface for a fixed period of time; and upon the expiration of the fixed period of time providing a **second positive airway pressure** to the patient breathing interface” (claim 21). (Emphasis added).

With respect to the 61 lines of Daniels' text the Office Action cites as disclosing the above claimed limitations, this text is primarily associated with the logic of the flow chart of Figure 11 and how it can be used in connection with **determining respiratory mechanic parameters** in “instances where a respiratory ventilator controls a patient's breathing.” (Col. 10, lines 50-54). It respectfully submitted that neither this disclosure nor the disclosures in the remaining lines of cited text disclose on their face the claimed “increasing and decreasing of breathing gas pressure **maintaining a positive pressure sufficient to sustain open the airway of a patient wearing the breathing interface**” (claims 1, 10 & 17) or “providing a **first positive airway pressure** to the patient breathing interface for a fixed period of time; and upon the expiration of the fixed period of time providing a **second positive airway pressure** to the patient breathing interface” (claim 21). (Emphasis added). As described above, the remaining disclosures are associated with Figure 11 and the **respiratory mechanic parameters** that are calculated.

Therefore, it is respectfully submitted that independent claims 1, 10, 17, and 21 are patentable.

Independent Claim 22

Independent claim 22 stands rejected as being obvious under 35 U.S.C. § 103 in view of the combination of U.S. Pat. No. 5,954050 to Christopher and U.S. Pat. No. 5,193,544 to Jaffe. It is well established that for a claimed invention to be rejected on obviousness grounds, all claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). In this regard, claim 22 is directed to a system for administering a breathing gas to a patient breathing interface that includes, for example:

logic for increasing and decreasing the level of the positive pressure breathing gas based on the level of carbon-dioxide detected to maintain open the airway of a patient. (Emphasis added).

It is respectfully submitted that neither Christopher nor Jaffe teach or suggest such a limitation.

The primary focus of Christopher is to **diagnose** sleep disorders (col. 8, line 58) using breathing supplied at a **constant flow rate** (col. 3, line 59 and col. 5, line 32.) Moreover, while Christopher does indicate that capnography (CO₂ monitoring) (col. 6, lines 53-55) can be used to **optimize** the flow rate and oxygen content of the breathing gas, it wholly fails to suggest how this optimization should be done. The Office Action asserts that Christopher's "logic 60" discloses the claimed logic for "increasing and decreasing the level of the positive pressure breathing gas based on the level of carbon-dioxide detected to maintain open the airway of a patient." Turning to Christopher, reference numeral 60 denotes "a computer processor 60 having a conventional display and control panel 62." (Col. 5, lines 14-16). As a whole, Christopher fails to suggest a gas supply system which includes **logic** for increasing and decreasing the **pressure** of the

breathing gas based on the level of detected CO₂ to thereby **maintain an open airway in the patient**, as required by claim 22.

The remaining references, Jaffe and Smythe et al., fail to cure the deficiencies in Christopher and Daniels. Jaffe and Smythe et al. at most disclose certain elements of equipment that can be used in a gas supply system. However, neither suggests **controlling** a gas supply system in the manner required by claim 22 or the other independent claims in this case. Accordingly, it is respectfully submitted that, even considering all references in combination, the gas supply system as recited in claim 22 and its method of use as recited in claims 1, 10, 17 and 21 are patentable.

The Dependent Claims

The dependent claims are respectfully submitted to be patentable at least because they incorporate the limitations of their respective independent claims.

CONCLUSION

Based on the foregoing amendments and remarks, the Applicant believes that all of the claims in this case are now in a condition for allowance and an indication to that effect is earnestly solicited. Furthermore, if the Examiner believes that additional discussions or information might advance the prosecution of this case, the Examiner should feel free to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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